RECORD AND BRIEFS.

Supreme Court, U.S.
FILED
FEB 17 2017
OFFICE OF THE CLERK

No. 15-1039

In the Supreme Court of the United States

SANDOZ, INC.,
Petitioner,

v.

AMGEN, INC., ET AL.,
Respondents.

On Writ of Certiorari to the
U.S. Court of Appeals for the Federal Circuit

BRIEF FOR AARP, AARP FOUNDATION, CITIZENS AGAINST GOVERNMENT WASTE, THE UAW RETIREE MEDICAL BENEFITS TRUST, THE NATIONAL HEALTH LAW PROGRAM, AND THE COALITION TO PROTECT PATIENT CHOICE AS AMICI CURIAE IN SUPPORT OF PETITIONER SANDOZ, INC.

William Alvarado Rivera*
**Counsel of Record*
AARP FOUNDATION LITIGATION
601 E Street, N.W.
Washington, D.C. 20049
Tel. (202) 434-3392
warivera@aarp.org
Counsel for Amici Curiae

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42 U.S.C. § 262(k)(3) 14
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42 U.S.C. § 262(l)(8) 11, 14
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Legislative History

Assessing the Impact of a Safe and Equitable Biosimilar Policy in the United States: Hearing Before the H. Subcomm. on Health of the Comm. on Energy and Commerce, 110th Cong. (May 2, 2007) 12, 15, 16

Biologics and Biosimilars: Hearing Before the House Subcomm. on Courts and Competition Pol'y 111th Cong. (July 14, 2009) 16

Examining Food and Drug Administration Follow-On Biologics: Hearing Before the S. Comm. on Health, Education, Labor, and Pensions, 110th Cong (March 8, 2007) 13

Other Authorities

AARP Pub. Pol'y Inst., *A Sense of Déjà Vu: The Debate Surrounding State Biosimilar Substitution Laws* (Sept. 2014), http://www.aarp.org/content/dam/aarp/research/public_policy_institute/health/ 2014/the-debate-surrounding-state-biosimilar-substitution-laws-AARP-ppi-health.pdf 11

AARP Pub. Pol'y Inst., *Biologics in Perspective: The Case for Generic Biologic Drugs* (May 2009), http://assets.aarp.org/rgcenter/health/fs155_biologics.pdf 8

AARP Pub. Pol'y Inst., *Biologics in Perspective: The New Biosimilar Approval Pathway* (Oct. 2011), http://assets.aarp.org/rgcenter/ppi/health-care/fs238.pdf. 8

Amgen, Inc., *About Neupogen*, http://www.neupogen.com/about/ (*last accessed* Feb. 13, 2017). 4

Nathan A. Berger, et al., *Cancer in the Elderly*, 117 Transactions of the Am. Clinical & Climatological Ass'n 147 (2006), https://www. ncbi.nlm.nih.gov/pmc/ articles/PMC1500929/pdf/tacca117000147.pdf 6

Erwin A. Blackstone and Joseph P. Fuhr, *The Economics of Biosimilars*, 6 Am. Health & Drug Benefits 469 (Sept./Oct. 2013), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4031732/pdf/ahdb-06-469.pdf 7, 8

Krista Carver, et al., *An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of* 2009, 65 Food and Drug L. J. 671 (2010) 12, 13, 15

Cong. Budget Ofc., *Cost Estimate: Biologics Price Competition and Innovation Act of 2007* (June 25, 2008), https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/costestimate/s16950.pdf. 9

Ctr. for Drug Eval. and Research, *List of Licensed Biological Products* (*last updated* Dec. 15, 2016), http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/UCM439049.pdf 11

Ctrs. for Disease Control & Prevention, *Arthritis-Related Statistics* (*last accessed* Feb. 14, 2017), https://www.cdc.gov/arthritis/ data_ statistics/arthritis-related-stats.htm 6, 7

Ctrs. for Disease Control & Prevention, *Health, United States, 2015: With Special Feature on Racial and Ethnic Health Disparities*, 168 and 272, tbls. 39 and 79 (2016), http://www.cdc.gov/nchs/data/hus/hus15.pdf. 5

Express Scripts, *The $250 Billion Potential of Biosimilars* (April 23, 2013), http://lab.express-scripts.com/lab/insights/industry-updates/the-$250-billion-potential-of-biosimilars. 10

Generics and Biosimilars Initiative, *Biosimilars Approved in the U.S. (last updated* Sept. 30, 2016), http://www.gabionline.net/ Biosimilars/General/ Biosimilars-approved-in-the-US 4

IMS Inst. for Healthcare Informatics, *Delivering on the Potential of Biosimilar Medicines: The Role of Functioning Competitive Markets* (Mar. 2016), http://www.imshealth.com/ files/web/IMSH%20 Institute/Healthcare%20Briefs/ Documents/IMS_Institute_Biosimilar_ Brief_March_2016.pdf..... 8, 9

Steven Kozlowski, et al., *Developing the Nation's Biosimilar Program*, 365 New Eng. J. Med. 385 (Aug. 4, 2011), http://www. nejm.org/doi/pdf/10.1056/ NEJMp1107285..... 6, 16, 17

Letter from AARP to Federal Trade Commission Re: Emerging Health Care Competition and Consumer Issues – Comment, Project No. P083901 (Dec. 22, 2008), https://www.ftc.gov/sites/default/files/documents/public_ comments/emerging-health-care-competition-and-consumer-issues-537778-00034/537778-00034.pdf 7

Francis Megerlin, et al., *Biosimilars and the European Experience: Implications for the United States*, 32 Health Aff. 1803 (Oct. 2013) 7

QuintilesIMS, *Biosimilars by Region—Europe* (*last accessed* Feb. 14, 2017), http://www.quintiles.com/microsites/biosimilars-knowledge-connect/biosimilars-by-region/europe 10

Rand Corp., *The Cost Savings Potential of Biosimilar Drugs in the United States* (2014), http:// www.rand.org/pubs/perspectives/PE127.html 9

Reuters, *Novartis Launches First U.S. "Biosimilar" Drug At 15 Percent Discount* (Sept. 3, 2015), http://www.reuters.com/article/us-novartis-drug-idUSKCN0R30C220150903 9

Sen. Comm. On Health, Education, Labor, and Pensions, *Press Release: Lawmakers Praise Committee Passage of Biologics Legislation* (June 27, 2007), http://www.help.senate.gov/ranking/newsroom/press/ lawmakers-praise-committee-passage-of-biologics-legislation 15

Mustaqeem Siddiqui, M.D., et al., *The High Cost of Cancer Drugs and What We Can Do About It*, 87 Mayo Clin. Proc. 935 (Oct. 2012), https:// www.ncbi.nlm.nih.gov/pmc/articles/ PMC3538397/pdf/main.pdf 8

U.S. Dep't of Health and Human Servs., Ofc. of Asst. Sec'y for Planning and Evaluation, *Observations on Trends in Prescription Drug Spending*, (Mar. 8, 2016), https://aspe.hhs.gov/sites/default/files/pdf/187586/Drugspending.pdf 5

U.S. Dept. of Health and Human Servs., Nat. Ctr. for Health Stats., *Strategies Used by Adults to Reduce Their Prescription Drug Costs: United States, 2013* (Jan. 2015), https://www.cdc.gov/nchs/data/databriefs/db184.pdf 6

U.S. Food and Drug Administration, *Biosimilars Implementation: Hearing Before Subcomm. on Health of the Comm. on Energy and Commerce, U.S. House of Representatives* 2 (Feb. 4, 2016) (testimony of Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research), http://www.fda.gov/downloads/NewsEvents/Testimony/UCM485049.pdf. 17

INTERESTS OF AMICI CURIAE[1]

AARP is a nonprofit, nonpartisan organization dedicated to fulfilling the needs and representing the interests of people age fifty and older. AARP fights to protect older people's financial security, health, and well-being. AARP's charitable affiliate, AARP Foundation, creates and advances effective solutions that help low-income individuals fifty and older secure the essentials. Among other things, AARP and AARP Foundation advocate for prompt consumer access to lower-cost prescription drugs, including through participation as amici curiae in federal courts. *E.g.*, *Fed. Trade Comm'n v. Actavis*, 133 S. Ct. 2223 (2013); *N.Y. v. Actavis*, 787 F.3d 638 (2d Cir. 2015); *King Drug Co. of Florence v. SmithKline Beecham Corp*, 791 F.3d 388 (3d Cir. 2015).

Citizens Against Government Waste (CAGW) is a 501(c)(3) private, nonpartisan, nonprofit organization representing more than 1 million members and supporters nationwide. CAGW works to eliminate waste, fraud, abuse, and mismanagement in government through research and public education activities. Founded in 1984 by the late businessman J. Peter Grace and late Pulitzer Prize-winning columnist Jack Anderson, CAGW is the legacy of President Ronald Reagan's Private Sector Survey on Cost Control, also known as the

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[1] No counsel for a party authored this brief in whole or in part or made a monetary contribution to fund the preparation or submission of this brief. No persons other than amici, their members, or their counsel made such a monetary contribution. Counsel for the parties consented to the filing of this brief.

Grace Commission. CAGW believes that competition and market forces are the best solutions for creating greater access to pharmaceuticals, encouraging more innovation, and lowering healthcare costs.

The UAW Retiree Medical Benefits Trust ("Trust") provides health care benefits for retired UAW members of General Motors, Ford, and Chrysler, along with their eligible dependents. This arrangement was made possible through a provision in the 2007 collective bargaining agreements between the UAW and the three auto companies under which all of the retiree health care liabilities were transferred to a new independent Voluntary Employee Beneficiary Association (VEBA). The Trust currently provides health care benefits to 703,807 persons. In addition to hospital and medical benefits, the Trust also provides prescription drug coverage to its enrollees. Nearly half of the Trust's annual expenditures are for prescription drug coverage. Many of the Trust's enrollees have complex medical needs and require specialty medications. As a result, biologic medical products are one of the fastest growing prescription drug costs for the Trust. Accordingly, the introduction and advancement of biologic medical products are important to the health and well-being of our enrollees. The Trust and its enrollees therefore have a significant interest in the rapid entry of lower cost biosimilar productions.

The National Health Law Program (NHeLP) is a 40-year old public interest law organization that engages in education, litigation, and policy analysis

to advance access to quality health care and protect the legal rights of low income people, people with disabilities, older adults, and other underserved populations. NHeLP works to help individuals and their advocates overcome barriers to health care, including access to necessary and affordable prescription drugs.

The Coalition to Protect Patient Choice (CPPC) is a non-incorporated coalition representing consumer interests united to protect patient choice in all healthcare markets. The CPPC advocates to protect consumers' ability to access quality healthcare, affordable health insurance, and lower-cost prescription drugs.

Amici submit this brief because the Federal Circuit misinterpreted the Biologics Price Competition and Innovation Act (BPCIA) to require an additional period of market exclusivity for biologics manufacturers beyond the twelve years already contemplated in the statute. The cost of any additional period of market exclusivity for prescription drugs is ultimately borne by consumers and taxpayers generally, and by older adults in particular. Amici do not address the issues raised in the cross-petition filed by Amgen. *Amgen, Inc. v. Sandoz, Inc.*, 794 F.3d 1347 (Fed. Cir. 2015), *cert. granted*, 85 U.S.L.W. 3343 (U.S. Jan. 13, 2017) (No. 15-1195).

SUMMARY OF ARGUMENT

Respondent Amgen manufactures Neupogen, a biologic drug commonly used to stimulate the body's production of white blood cells in patients undergoing chemotherapy. Amgen, Inc., *About Neupogen*, http://www.neupogen.com/about/ (*last accessed* Feb. 13, 2017). Approved by the Food and Drug Administration (FDA) in March 2015, Petitioner Sandoz's product Zarxio was the first biosimilar drug approved under the new pathway for licensing of biosimilars under the BPCIA. Generics and Biosimilars Initiative, *Biosimilars Approved in the U.S.* (*last updated* Sept. 30, 2016), http://www.gabionline.net/Biosimilars/General/Biosimilars-approved-in-the-US. As such, this case represents a critical juncture in the BPCIA's compromise between encouraging innovation and controlling costs of biologic drugs.

Biologic drugs represent a large and growing segment of the overall prescription drug market. Older adults, who as a group often require more daily prescription drugs and shoulder a higher share of the overall costs for these drugs, are particularly sensitive to the increasing prices of these life-saving medications. This is especially true in the biologics market, where the costs of the biologic vastly exceed those of traditional prescription drugs. In this context, the Court must be especially mindful of Congress's primary goals in passing the BPCIA – to facilitate prompt market entry of biosimilars to lower biologics costs while offering an incentive to produce new and innovative biologics in the future.

Respondent posits that biosimilar applicants can only provide the required notice of commercial marketing *after* the FDA approves the biosimilar for public distribution; the Court's adoption of this theory would unbalance Congress's careful compromise between competing demands and impose unnecessary barriers to lower-cost biosimilars.

ARGUMENT

I. BIOLOGIC DRUGS ARE OF CRITICAL IMPORTANCE TO CONSUMERS BUT IMPOSE A HIGH COST TO CONSUMERS AND TAXPAYERS GENERALLY AND TO OLDER ADULTS IN PARTICULAR.

In the past seven years alone, nationwide spending on prescription drugs is estimated to have increased by over $100 billion. U.S. Dep't of Health and Human Servs., Ofc. of Asst. Sec'y for Planning and Evaluation, *Observations on Trends in Prescription Drug Spending*, 8, tbl. 1 (Mar. 8, 2016), https://aspe.hhs.gov/sites/default/files/pdf/187586/Drugspending.pdf. A large portion of those costs are borne by older adults, who, as a group, have the highest rate of prescription drug use due to the higher incidence of chronic diseases amongst older adults. Ctrs. for Disease Control & Prevention, *Health, United States, 2015: With Special Feature on Racial and Ethnic Health Disparities*, 168 and 272, tbls. 39 and 79 (2016), http://www.cdc.gov/nchs/data/hus/hus15.pdf.

The pace of ever-increasing drug prices, as well as the increased share of costs borne by consumers, has

a direct impact on consumers' behavior. In addition to their obvious financial implications, high drug prices affect consumers' compliance with their medication regimen. According to the National Center for Health Statistics, consumers age 18-64 were almost twice as likely as adults age 65+ to skip doses, take less medication, or delay filling prescriptions to save money. U.S. Dept. of Health and Human Servs., Nat. Ctr. for Health Stats., *Strategies Used by Adults to Reduce Their Prescription Drug Costs: United States, 2013*, 2 (Jan. 2015), https://www.cdc.gov/nchs/data/databriefs/db184.pdf. Individuals age 18-64 who are either uninsured or have coverage through Medicaid are more likely to unilaterally curtail their prescription drug usage, even against the explicit instructions of their physician. *Id.* at 3. The poorest Americans—regardless of their age—are also more likely to avoid taking their prescription drugs as prescribed to limit costs. *Id.* at 4-5.

Biologics are quickly emerging as a vital tool in the fight against many chronic and life-threatening conditions that acutely or disproportionately affect older adults, including arthritis and cancer. Steven Kozlowski, et al., *Developing the Nation's Biosimilar Program*, 365 New Eng. J. Med. 385, 386 (Aug. 4, 2011), http://www.nejm.org/doi/pdf/10.1056/NEJMp1107285. *See also* Nathan A. Berger, et al., *Cancer in the Elderly*, 117 Transactions of the Am. Clinical & Climatological Ass'n 147, 148 (2006), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1500929/pdf/tacca117000147.pdf (stating that "persons over 65 account[] for 60% of newly diagnosed [malignant cancers] and 70% of all cancer deaths") *and* Ctrs. for Disease Control &

Prevention, *Arthritis-Related Statistics* (*last accessed* Feb. 14, 2017), https://www.cdc.gov/arthritis/data_statistics/arthritis-related-stats.htm (finding that "the risk of arthritis increases with age").

Unfortunately, the potential of biologics to treat life-threatening conditions comes at a steep cost to consumers, taxpayers, and insurers, as the prices for these drugs far exceed those of traditional prescription drugs, with some companies charging $200,000 a year or more. Francis Megerlin, et al., *Biosimilars and the European Experience: Implications for the United States*, 32 Health Aff. 1803 (Oct. 2013). Even among insured individuals with prescription drug coverage, a consumer's out-of-pocket cost for biologics tends to be higher than many traditional prescription drugs, as biologics are frequently placed on higher cost-sharing tiers that impose higher co-pays or co-insurance requirements of up to 50% of the drug's price. *Letter from AARP to Federal Trade Commission Re: Emerging Health Care Competition and Consumer Issues – Comment, Project No. P083901*, 2 (Dec. 22, 2008), https://www.ftc.gov/sites/default/files/documents/public_comments/emerging-health-care-competition-and-consumer-issues-537778-00034/ 537778-00034.pdf.

Increasing demand for biologic drugs has allowed them to buck general downturns in prescription drug spending trends. In 2012, while overall U.S. spending on prescription drugs decreased from the preceding year, spending on so-called "specialty drugs," mostly biologics, continued to climb by nearly 20%. Erwin A. Blackstone and Joseph P. Fuhr, *The Economics of Biosimilars*, 6 Am. Health &

Drug Benefits 469, 473 (Sept./Oct. 2013), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4031732/pdf/ahdb-06-469.pdf. Biologics manufacturers frequently argue that their prices merely reflect higher costs of obtaining approval for and manufacturing a biologic. *See, e.g.*, Mustaqeem Siddiqui, M.D., et al., *The High Cost of Cancer Drugs and What We Can Do About It*, 87 Mayo Clin. Proc. 935, 936 (Oct. 2012), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3538397/pdf/main.pdf. (estimating "$1.2 billion to $1.3 billion in cash outlays" per approved biologic). Nonetheless, the high prices charged for biologics can allow their manufacturers to recoup development costs within a single year. AARP Pub. Pol'y Inst., *Biologics in Perspective: The New Biosimilar Approval Pathway* (Oct. 2011), http://assets.aarp.org/rgcenter/ppi/health-care/fs238.pdf.

With over 250 biologic drugs currently on the market and approximately 300 in development, the role of biologics in the health care system continues to expand with each passing year. AARP Pub. Pol'y Inst., *Biologics in Perspective: The Case for Generic Biologic Drugs* (May 2009), http://assets.aarp.org/rgcenter/health/fs155_biologics.pdf. Not only does the number of biologics continue to grow, but manufacturers of existing biologic drugs also seek approval to use them in treating additional diseases. For example, manufacturers of the biologic Avastin, originally approved in 2004 in the treatment of colon, lung, and breast cancers, sought FDA approval for the use of Avastin to treat 23 additional diseases. *Id.* By 2020, biologics are expected to account for 28% of the global prescription drug market. IMS Inst. for Healthcare Informatics, *Delivering on the Potential of Biosimilar*

Medicines: The Role of Functioning Competitive Markets, 1 (Mar. 2016), http://www.imshealth.com/files/web/IMSH%20Institute/Healthcare%20Briefs/Documents/IMS_Institute_Biosimilar_Brief_March_2016.pdf.

Given the prominent and growing role of biologics in the health care system, it is vital to consumers and taxpayers that the marketplace allows for the prompt entry of competing products that would lower the prices of—and thus, increase access to—these drugs. Competition between biologics and biosimilars has a demonstrable effect on prices for these drugs. For example, in the course of this litigation, Zarxio initially sought to enter the market at a 15% discount off the price of Neupogen. Reuters, *Novartis Launches First U.S. "Biosimilar" Drug At 15 Percent Discount* (Sept. 3, 2015), http://www.reuters.com/article/us-novartis-drug-idUSKCN0R30C220150903.

At the time of the BPCIA's passage, the Congressional Budget Office estimated that the Act would save consumers, taxpayers, and insurers approximately $25 billion between 2009 and 2018. Cong. Budget Ofc., *Cost Estimate: Biologics Price Competition and Innovation Act of 2007* (June 25, 2008), https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/costestimate/s16950.pdf. More recent estimates show that biosimilars have the potential to save the U.S. health care system $44.2 billion by 2024. Rand Corp., *The Cost Savings Potential of Biosimilar Drugs in the United States* (2014), http://www.rand.org/pubs/perspectives/PE127.html. Other stakeholders predict even greater savings

from biosimilars. For example, a recent analysis by Express Scripts, one of the nation's largest pharmacy benefit managers, predicts that U.S. consumers, taxpayers, and insurers would save $250 billion by 2024 if the 11 biosimilars most likely to enter the market actually did so. Express Scripts, *The $250 Billion Potential of Biosimilars* (April 23, 2013), http://lab.express-scripts.com/lab/insights/industry-updates/the-$250-billion-potential-of-biosimilars.

Although biosimilars are a relatively new development in the U.S. health care system, the European experience with biosimilars may provide some insight as to the cost savings achieved by prompt consumer access to biosimilars. Since European authorities approved the first biosimilar in 2006, biosimilars have proven to increase both access and cost effectiveness. QuintilesIMS, *Biosimilars by Region—Europe* (*last accessed* Feb. 14, 2017), http://www.quintiles.com/microsites/biosimilars-know ledge-connect/biosimilars-by-region/europe. By 2013, biosimilars comprised approximately 25 percent of total sales of biologics with expired European Union patents. *Id.* Between 2006 and 2014, biosimilars increased patient access to biologics by 44 percent in France, Germany, Italy, Spain and the U.K. *Id.* Furthermore, the availability of biosimilars resulted in mean price discounts of 15 to 40 percent off the prices of the original biologics. *Id.*

This case comes before the Court during an unprecedented opportunity for more widespread entry of biosimilars to compete with and lower the cost of biologics. While the FDA has approved only four

biosimilars through the BPCIA process to date, by 2019, biologics with a combined market value of $50 billion are expected to lose protection of their underlying patents. Ctr. for Drug Eval. and Research, *List of Licensed Biological Products* (*last updated* Dec. 15, 2016), http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/UCM439049.pdf; AARP Pub. Pol'y Inst., *A Sense of Déjà Vu: The Debate Surrounding State Biosimilar Substitution Laws* (Sept. 2014), http://www.aarp.org/content/dam/aarp/research/public_policy_institute/health/2014/the-debate-surrounding-state-biosimilar-substitution-laws-AARP-ppi-health.pdf. If the Court adopts the interpretation of the BPCIA proposed by Respondent Amgen, the chance for consumers and taxpayers to benefit from the cost savings brought on by broader market entry of biosimilars will be unnecessarily delayed.

II. THE FEDERAL CIRCUIT'S RULING UPSETS CONGRESS'S INTENDED BALANCE BETWEEN ENCOURAGING INNOVATION AND CONTROLLING COSTS.

As this Court has made abundantly clear, the "words of a statute must be read in their context and with a view to their place in the overall statutory scheme." *King v. Burwell*, 135 S. Ct. 2480, 2492 (2015). The Federal Circuit's opinion holds that a biosimilar applicant "may only give effective notice of commercial marketing [under 42 U.S.C. § 262(l)(8)] *after* the FDA has licensed its product." *Amgen, Inc.*

v. Sandoz, Inc., 794 F.3d 1347, 1357 (Fed. Cir. 2015) (emphasis added). Judge Chen's dissenting opinion correctly frames this holding as a "180-day exclusivity windfall" for biologics manufacturers that appears nowhere in the actual statute. *Id.* at 1371 (Chen, J., dissenting in part). The Federal Circuit's opinion on this point has no basis in the text or structure of the BPCIA and is contrary to Congress's explicit objectives in its passage.

As with the Hatch-Waxman Amendments that concern the approval of generic drugs and resulting patent litigation process, the process outlined in the BPCIA resolves questions as to the timing and degree of overlap between the resolution of patent disputes and the FDA's approval process. *See* 21 U.S.C. § 355(j) (describing the process for approval of generic drugs). When Congress initially considered establishing a "pathway" for approval of biosimilars, these issues led to widely divergent opinions. Some stakeholders testified that the process agreed upon by Congress should include "a mechanism for allowing generic companies to resolve certain patent disputes without delaying FDA approval." *Assessing the Impact of a Safe and Equitable Biosimilar Policy in the United States: Hearing Before the H. Subcomm. on Health of the Comm. on Energy and Commerce*, 110th Cong., 117 (May 2, 2007) (hereinafter *Assessing the Impact*) (testimony of Bruce Downey, Chairman, Generic Pharmaceutical Association). Others concluded that the "biosimilar applications should not be approved until all patent disputes had been resolved." Krista Carver, et al., *An Unofficial Legislative History of the Biologics*

Price Competition and Innovation Act of 2009, 65 Food and Drug L. J. 671, 736 (2010) (hereinafter *Unofficial History*) (summarizing the testimony of David Schenkein, M.D., Vice President of Clinical Hematology and Oncology at Genentech, Inc.). Others proposed a total "decoupling" of the patent litigation process from the biosimilar licensure process. *Examining Food and Drug Administration Follow-On Biologics: Hearing Before the S. Comm. on Health, Education, Labor, and Pensions*, 110th Cong., 36 (March 8, 2007) (testimony of Ajaz S. Hussain, Ph.D., Vice President of Biopharmaceutical Development, Novartis). As enacted, the BPCIA adopts Dr. Hussain's approach.

The structure of the BPCIA belies Respondent's argument that the 180-day notice of a manufacturer's intent to market a biosimilar can only be provided *after* the FDA approves the application to license the biosimilar. The process and standards by which the FDA can license biosimilars are described at length at 42 U.S.C. § 262(k). Innovator biologics manufacturers enjoy both a twelve-year period of market exclusivity, as well as a four-year ban on the submission of applications to license a biosimilar. 42 U.S.C. § 262(k)(7). This section also describes the mandatory contents of an application to produce a biosimilar, as well as the standards by which a biosimilar can be deemed "interchangeable" with the biologic. 42 U.S.C. § 262(k)(2)-(4). However, at no point does this section purport to govern the resolution of patent infringement claims that may be filed during this process.

The resolution of patent litigation that may be triggered by an application to produce a biosimilar under 42 U.S.C. § 262(k) is described separately in the statute. 42 U.S.C. § 262(l). This process has its own specific timeframes and expectations of litigants at various points in the litigation process. 42 U.S.C. § 262(l)(1)-(7). This section does not describe or dictate the standards for approval of a biosimilar applicant, nor does it purport to alter the periods of market exclusivity granted to biologics manufacturers. Only at the end of this section is there language that tangentially references the outcome of the FDA's approval process. 42 U.S.C. § 262(l)(8)(A). However, in context, this language merely reflects a practical consideration that biosimilars must be, in fact, approved by the FDA before commercial marketing of biosimilars can actually begin.

The most sensible way to interpret the notice of commercial marketing provision in 42 U.S.C. § 262(l)(8) is that the process by which the FDA licenses a biosimilar under subsection (k) runs *parallel* to the patent litigation process under subsection (l). Ultimately, the FDA must approve the biosimilar before it can be marketed to the public, irrespective of where the parties are in the patent litigation process. 42 U.S.C. § 262(k)(3). Congress did not intend to penalize biosimilars manufacturers for their readiness to bring their products to market immediately upon their approval by the FDA.

Congress knew of the complexities of patent litigation in the pharmaceutical context when it

enacted the BPCIA. To speed up the market entry of biosimilars, Congress adopted the proposal by some stakeholders that the process designed by Congress should not "force[]" biosimilars manufacturers "to litigate every patent relating to the brand product" in order to clear the way for a biosimilar's launch. *Assessing the Impact* at 119 (testimony of Bruce Downey). In other words, Congress adopted the view proposed by some stakeholders that the BPCIA should contain "a mechanism for litigating only those patent disputes that the generic company believes would delay its launch," because litigation of other patents would cause "unnecessary delay." *Unofficial History* at 736. According to the Biotechnology Innovation Organization, the purpose of granting market exclusivity to a biologics manufacturer would be to provide an "insurance policy" for "instances where the [biosimilar] manufacturer is able to work around the patents held by the innovator but still gain approval of its [biosimilar]." *Id.* at 727. It has nothing to do with the status of the FDA's approval of the biosimilar.

Congress intended the BCPIA to represent a "balanced approach" between satisfying the need for affordable, safe, and effective biosimilars with the need to incentivize innovation by biologics manufacturers. Sen. Comm. On Health, Education, Labor, and Pensions, *Press Release: Lawmakers Praise Committee Passage of Biologics Legislation* (June 27, 2007), http://www.help.senate.gov/ranking/newsroom/press/lawmakers-praise-committee-passage-of-biologics-legislation; *see also Assessing the Impact* at 19 (statement of Rep. Towns). To that end,

Congress envisioned a process to facilitate FDA approval of biosimilars, while abbreviating patent litigation in a manner comparable to the system that exists for generic drugs under the Hatch-Waxman Act, with the ultimate goal to produce "measurable savings" to consumers, taxpayers, and insurers. *Assessing the Impact* at 2 (statement of Rep. Pallone).

Congress intended the BPCIA's twelve years of commercial marketing exclusivity for biologics manufacturers to represent a rough approximation of the average years of market exclusivity already enjoyed by biologics manufacturers. *Biologics and Biosimilars: Hearing Before the House Subcomm. on Courts and Competition Pol'y* 111th Cong., 8 (July 14, 2009) (testimony of Rep. Eshoo). At that time, Congress considered widely varying proposals for market exclusivity, with some stakeholders recommending a period of as long as 14 years, and others recommending a period as short as five to seven years. *Unofficial History* at 817. The twelve years ultimately settled on by Congress represents the culmination of years of negotiations between various stakeholders.

For its part, the FDA views its own responsibilities as independent of the patent litigation and market exclusivity issues described above. In the words of the FDA's Center for Drug Evaluation and Research, the BPCIA is merely a mechanism to "improve access" to biosimilars by creating an "abbreviated pathway" to their licensure that "will eliminate unnecessary...testing of biosimilars in animals and humans." Kozlowski,

supra at 385. In the FDA's view, the process established by the BPCIA "permits a biosimilar...to rely on certain existing scientific knowledge about the safety and effectiveness of the [original biologic]...saving the sponsor time and resources and thereby encouraging price competition and lower consumer healthcare costs." U.S. Food and Drug Administration, *Biosimilars Implementation: Hearing Before Subcomm. on Health of the Comm. on Energy and Commerce, U.S. House of Representatives*, 2 (Feb. 4, 2016) (testimony of Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research), http://www.fda.gov/downloads/NewsEvents/Testimony/UCM485049.pdf. As it continues to apply the approval process described by the BPCIA, the FDA's concern strictly rests with "earn[ing] and sustain[ing] both physicians' and patients' confidence in biosimilar and interchangeable products [by applying] a scientifically rigorous review process and approval standard." *Id.* at 1.

CONCLUSION

As the Northern District of California observed in this case, if Congress truly intended to extend an additional 180 days of market exclusivity to biologics, "it could not have chosen a more convoluted method of doing so." *Amgen, Inc. v. Sandoz, Inc.*, 2015 U.S. Dist. LEXIS 34537, *25 (Mar. 19, 2015). The Federal Circuit's opinion creates unnecessary delays to public access of biosimilars, and in so doing harms consumers and taxpayers. Because Congress had no

intention to do so, the Federal Circuit's decision to the contrary should be reversed.

Respectfully submitted,

William Alvarado Rivera*
**Counsel of Record*
AARP FOUNDATION LITIGATION
601 E Street, N.W.
Washington, D.C. 20049
Tel. (202) 434-3392
warivera@aarp.org
Counsel for Amici Curiae